

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the VentFree Respiratory Muscle Stimulator During the COVID-19 Pandemic

May 1, 2020

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the VentFree Respiratory Muscle Stimulator (hereafter referred to as 'VentFree').

All patients who are treated with VentFree during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of the VentFree Respiratory Muscle Stimulator During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage (link provided below) for the most up to date information.

What do I need to know about the emergency use of VentFree?

- Devices that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- VentFree has been authorized for use in healthcare setting for treatment of mechanically ventilated adult patients during the COVID-19 pandemic by their healthcare provider.
- VentFree is intended to be used by healthcare professionals in a healthcare facility to treat adult patients by reducing disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation.
- VentFree is recommended until successful weaning or for no more than 6 weeks, whichever comes first.

- Healthcare providers should review the applicable VentFree Respiratory Muscle Stimulator User Manual- Model A or VentFree Respiratory Muscle Stimulator User Manual- Model B, and other labeling information.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of VentFree?

Potential benefits of VentFree:

- Treatment can start soon after intubation when patients may be sedated
- Prevention or retardation of disuse atrophy of the abdominal wall muscles
- Reduced time to weaning from mechanical ventilation
- Avoidance of risks of prolonged mechanical ventilation such as ventilator associated pneumonia (VAP), ventilator associated lung injury (VALI), muscle wasting, laryngotracheal injury, and death

Potential risks of VentFree:

- Patient discomfort during treatment
- Elevated blood pressure during treatment
- Elevated respiratory rate during treatment
- Muscle soreness
- Skin irritation and burns beneath the electrodes

What are the main contraindications or warnings for VentFree?

The contraindications for VentFree:

- Do not use with demand type implanted pacemaker or defibrillator
- Do not use electrical stimulation over pregnant uterus

Report adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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- Do not use on a patient with recent abdominal surgery with open abdominal wounds
- Do not use on open or damaged skin
- Do not use on patients under 18 years of age

The main warnings for VentFree:

- VentFree should not be used as a replacement for a mechanical ventilator
- The VentFree electrodes and flow sensor should not be shared between patients, but may be reused on the same patient
- Electrodes should only be placed on the abdomen in compliance with the directions for use
- Electronic monitoring equipment (such as ECG and ECG alarms) may not operate properly when electrical stimulation is in use

What are the alternatives to VentFree and the known and potential benefits and risks of such products?

Alternatives to VentFree that is authorized under this Emergency Use Authorization (EUA) include “traditional” weaning strategies based on manipulation of ventilator settings modes which allow or encourage gradually increased patient effort and stamina for breathing.

Benefits associated with “traditional” weaning strategies:

- Non-invasive
- Healthcare provider familiarity with standard ventilator weaning strategies, including those described in clinical guidelines

Risks associated with “traditional” weaning strategies:

- Prolonged mechanical ventilation with associated risk, such as ventilator associated pneumonia (VAP), ventilator associated lung injury (VALI), muscle wasting, laryngotracheal injury, and death

What is an EUA?

The United States (U.S.) FDA issued an Emergency Use Authorization (EUA) for VentFree when used to treat adult patients to reduce disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation in healthcare settings during the COVID-19 pandemic. The EUA is supported by a Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as

medical devices, due to shortages during the COVID-19 pandemic.

The authorized use of VentFree under this EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available, showing it is reasonable to believe that when used in the hospital setting, the VentFree may be effective in treatment of adult patients by reducing disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation in healthcare settings, as a result, may increase the availability of ventilators for other patients. The EUA for these devices are in effect for the duration of the COVID-19 pandemic, unless terminated or revoked (after which the device may no longer be used).

An FDA approved or cleared device should be used instead of the VentFree under EUA, when applicable and available.

Where can I go for updates and more information?

CDC Webpages:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Infection Prevention and Control Recommendations in Healthcare Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FDA webpages:

General: <http://www.fda.gov/novelcoronavirus>

EUAs: (includes links to patient fact sheet and manufacturer’s instructions)

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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